

an elongated, cylindrical sealing part moveable relative to the conduit between a closed position and an open position and adapted for sealing the conduit from an ambient atmosphere when in the closed position; and

an opening element including an outer socket connector having a diameter that is greater than a diameter of the conduit, the opening element configured to open the sealing part while forming a connection, wherein the opening element prevents the sealing part from contacting the conduit either when in the closed position or in the open position.

## **REMARKS**

### I. Introduction

Claims 1 to 17 are pending in the present application. By this amendment, claim 1 has been amended. In view of the above amendments and the following remarks, it is respectfully submitted that claims 1 to 17 are allowable, and reconsideration is respectfully requested.

### II. Response to §102(b) Rejections

Claims 1 to 3, 6 to 12, and 16 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,030,494 ("Tenczar"). Applicant submits that Tenczar does not anticipate claims 1 to 3, 6 to 12, and 16 for the following reasons.

Claim 1 relates to a connector element for connecting a fluid line, preferably a length of tubing, cannulas or catheters to a second connector element. The connector element includes a conduit forming a lumen for conveying a flowing medium. The connector element also includes an elongated, cylindrical sealing part, the sealing part being moveable relative to the conduit between a closed position and an open position, and being adapted for sealing the conduit from an ambient atmosphere when in the closed position. An opening element, in the form of an outer socket connector having a diameter that is greater than a diameter of the conduit, is configured to open the sealing part while forming a connection, wherein

the opening element prevents the sealing part from contacting the conduit either when in the closed position or in the open position.

Tenczar purports to relate to a connector means for conveying fluid from a supply source to a delivery location, the connectors having one conduit extending to the supply source and another conduit extending to the delivery location. Tenczar states that each terminal part has a cylindrical housing with a closed end to which the conduit is joined, and having an opposite operable end which is closed by a penetrable barrier, the barrier and closed end of the housing defining an interior environment safe from external contaminants. Tenczar also states that a male tubular coupler is in one housing, a female tubular coupler is in the other housing, and a penetrator element is disposed around one of the tubular connectors, the penetrable barriers having a film of covered adhesive and the exposed adhesive films being placed in face to face contact to coaxially align the housing parts and bond the barrier membranes to exclude the environment. According to Tenczar, the penetrator element pierces the adhering barriers by either moving the penetrator element from one housing into the coaxially aligned housing, or by telescoping the housing cylinders so that the adhering barriers are contacted by the fixed penetrator element. Tenczar states that the male tubular connector then engages the female tubular connector within a protected environment to effect connection between the supply source and the delivery location.

The Final Office Action states that "Tenczar discloses a connector element having a conduit 55, an inner socket connector 56, opening element 54 on an outer socket connector, housing 52, shut-off element 57 adapted for sealing the conduit, sealing part 58 having a cylindrical base body 63 and lock 60 that initially holds the barrier to the housing. See figs. 7, 8." Final Office Action at page 2.

Applicant respectfully submits that Tenczar does not anticipate the present claims because Tenczar fails to disclose, or even suggest, each and every element recited in amended claim 1. For instance, it is respectfully submitted that

Tenczar fails to disclose, or even suggest, an elongated, cylindrical sealing part, as recited in amended claim 1. The Specification states at page 4, lines 10 to 12, that:

“In another preferred embodiment of the present invention, the base body of the sealing part is a cylindrical shell and the membrane is arranged on one end of the base body.”  
Emphasis added.

The Specification describes at page 4, lines 12 to 17 and the Figures illustrate, an elongated sealing part wherein:

“The sealing part is advantageously used in such a way that the end area of the base body provided with the membrane of one connection element is oriented away from the ‘connection side’, which is the side of the connector element where the second connector element is inserted.” Emphasis added.

This arrangement provides additional advantages to a design that is not elongated or cylindrical in shape. Specifically, the Specification states at page 4, lines 17 to 23 that:

“This offers the advantage that a significant portion of the base body protects the membrane from contact, because the membrane is set back from the connection side end portion of the connector element by approximately the length of the base body. It is thus possible to prevent inadvertent contact between the membrane and the opening element of the second connector element.”  
Emphasis added.

Tenczar, on the other hand, describes at column 4, lines 42 to 44, that:

“[t]he assembly includes a penetrable barrier 58 which is held to the inside of the cylindrical housing by O-ring 60. An adhesive film 62 is provided on the face of the barrier. A substantially rigid pusher ring 63 supports the O ring and the barrier. The barrier assembly is movable against the penetrator 54.”

Tenczar goes on to describe at column 5, lines 4 to 8, that:

"[i]n operation, [the] membrane in the female terminal adheres to the barrier membrane recessed in the male terminal, and the bonded membranes, aided by pusher ring 63 and seal 60, are moved against the penetrator end 54."

Thus, Tenczar does not disclose or even suggest a cylindrically-shaped sealing part, since both O-ring 58 and pusher ring 63 have a ring shape. At most, Tenczar describes a ring-shaped sealing part. The Final Office Action states that "seal 58 [has] a cylindrical base 63 [and that having] a cylindrical base, the seal is cylindrical." However, nowhere in Tenczar are O-ring 58 and pusher ring 63 described as being anything other than ring-shaped, and certainly not as being cylindrical. Even assuming arguendo that O-ring 58 and pusher ring 63 of Tenczar could be construed as being cylindrical -- which the Applicant maintains they can not be -- claim 1 has been amended without prejudice herein to recite that the cylindrically-shaped sealing part is elongated. Neither the ring-shaped seal 58 nor the pusher ring 63 are described nor suggested as being elongated. As such, the non-cylindrical, non-elongated O-ring seal of Tenczar does not provide the advantage of the elongated, cylindrically-shaped sealing part of the present invention by protecting the membrane from contact and preventing inadvertent contact between the membrane and the opening element of the second connector element.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Tenczar does not disclose, or even suggest, an

elongated, cylindrical sealing part, as recited in amended claim 1. It is therefore respectfully submitted that Tenczar does not anticipate amended claim 1.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a “basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art.” See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Tenczar does not anticipate amended claim 1, and Applicant respectfully requests that the rejection of this claim be withdrawn.

As for claims 2 to 3, 6 to 12, and 16, each of which ultimately depends from claim 1 and therefore include all of the limitations of claim 1, it is respectfully submitted that Tenczar does not anticipate these dependent claims for at least the

same reasons given above in support of the patentability of amended claim 1, and Applicant respectfully requests that the rejection of these claims be withdrawn also.

III. Response to §103(a) Rejections

Claims 4 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tenczar in view of U.S. Patent No. 5,492,147 ("Challender et al."). Applicant respectfully submits that the combination of Tenczar and Challender et al. does not render these claims obvious.

Challender et al. purport to disclose a dry break connection for joining together opposing passageways. According to Challender et al., the connection has been designed to prevent moisture or liquid from being spilled or remain on opposing ends of the connection when the connection is separated.

Claims 4 and 5 depend from claim 1. It is respectfully submitted that the combination of Tenczar and Challender et al. does not disclose, or even suggest, all of the limitations recited in amended claim 1. As stated above, it is respectfully submitted that Tenczar does not disclose, or even suggest, an elongated, cylindrical sealing part, as recited in amended claim 1. Furthermore, Challender et al. is not relied on to disclose or suggest, and indeed do not disclose or suggest, an elongated, cylindrical sealing part that is moveable relative to the conduit between a closed position and an open position. Instead, Challender et al. describe a sealing part that is neither elongated nor cylindrical, and that is locked to housing 51 and that is not capable of moving relative to the conduit. Instead, the sealing part remains fixed between the exterior wall surface portion 44 and the inner wall portion 51 which does not move relative to the conduit.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837

F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As indicated above, it is respectfully submitted that the combination of Tenczar and Challender et al. does not disclose, or even suggest, all of the limitations recited in claim 1.

Moreover, it is respectfully submitted that the cases of In re Fine, supra, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Final Office Action's generalized assertions that it would have been obvious to modify or combine the reference do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Final Office Action reflects a subjective "obvious to try" standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the reference relied upon. In particular, the Court in the case of In re Fine stated that:

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done. . . .

**Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.**

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .

**Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill . . . would have been motivated to make the modifications . . . necessary to arrive at the claimed [invention].**

In re Jones, 21 U.S.P.Q.2d at 1943, 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Final Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art would be motivated to modify or combine reference to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for modifying or combining the references to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a "technologically simple concept" – which is not the case here -- there still must be some finding as to the "specific understanding or principle within the knowledge of a skilled artisan" that would motivate a person having no knowledge of the claimed subject matter to "make the combination in the manner claimed," stating that:

In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific

understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

In summary, it is respectfully submitted that the combination of Tenczar and Challender et al. does not disclose, or even suggest, all of the limitations recited in amended claim 1.

Claims 4 and 5 ultimately depend from claim 1 and include all of the limitations thereof. Because the combination of Tenczar and Challender et al. does not disclose or suggest all of the limitations of claims 4 and 5, it is submitted that these claims are not rendered obvious thereby. In re Fine, supra (any dependent claim that depends from a non-obvious independent claim is non-obvious).

#### **IV. Allowed Claims**

Applicant notes with appreciation the Examiner's finding that claims 13 to 15 and 17 are allowed.

#### **V. Conclusion**

Attached hereto is a marked-up version of the changes made to the claims by the current Reply Under 37 C.F.R. §1.116. The attached page is captioned "**Version with Markings to Show Changes Made.**"

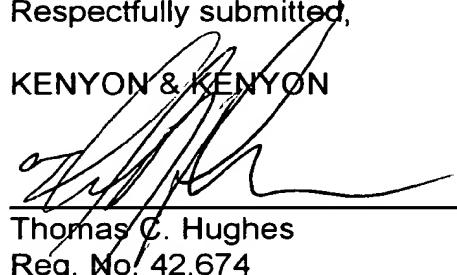
Applicant submits that this application is in condition for allowance and respectfully requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's representative, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

KENYON & KENYON

Dated: June 27, 2003

By:

  
Thomas C. Hughes  
Reg. No. 42,674

One Broadway  
New York, New York 10004  
(212) 425-7200

**Version with Markings to Show Changes Made**

**IN THE CLAIMS:**

Claim 1 has been amended without prejudice as follows:

1. (Three Times Amended) A connector element for connecting a fluid line, preferably a length of tubing, cannulas or catheters to a second connector element, comprising:

a conduit forming a lumen for conveying a flowing medium;

an elongated, [a] cylindrical sealing part moveable relative to the conduit between a closed position and an open position and[.] adapted for sealing the conduit from an ambient atmosphere when in the closed position; and

an opening element including an outer socket connector having a diameter that is greater than a diameter of the conduit, the opening element configured to open the sealing part while forming a connection, wherein the opening element prevents the sealing part from contacting the conduit either when in the closed position or in the open position.